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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,390	08/21/2003	Mitinori Saitou	674558-2002.1	1543

20999 7590 10/19/2005

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EXAMINER	
GAMETT, DANIEL C	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,390	SAITOU ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *8-22,25 and 28-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,23,24,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Claims 2-7, 24, and 27 in total, and claims 1, 23, and 26 in part, drawn to the GCRI (Fragilis) polypeptide, in the reply filed on 08/03/2005 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search groups that are commonly classified. This is not found persuasive because, for example, as of this writing, class 530 comprises 36764 issued patents and 15869 published pending applications. In biotechnology, searching relies heavily on key words, concepts, and components. The placement of two inventions into separate classes indicates a different status in the art, which means that different key concepts, vocabulary, and modes of action are contemplated, and so the searches will necessarily be divergent. The fact that two inventions can be put into a single class, or subclass, does not mean that a search for one would be coextensive with the search for the other. Unique chemical structures, such as nucleic acid or polypeptide sequences, require separate searches and each molecule has its own questions of patentability to be addressed.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-22, 25, and 28-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/03/2005.

3. Claims 1-7, 23, 24, 26, and 27 are under examination insofar as they read upon the GCRI (Fragilis) polypeptide.

Claim Objections

4. Claims 1, 23, 24, 26, and 27 are objected to because of the following informalities: Claim 1 recites nonelected subject matter, specifically "a GCR2 polypeptide". Claims 23 and 24 are dependent from nonelected claims. Claims 26 and 27 recite nonelected subject matter, specifically SEQ ID NO: 4. Applicant is required to cancel or amend the claims to remove nonelected subject matter and to remove dependency from nonelected claims. Appropriate correction is required.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-7, 23, 24, 26, and 27 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 23, 24, 26, and 27 of copending Application No. 10621911. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-7, 23, 24, 26, and 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn a polypeptide comprising the amino acid sequence shown in SEQ ID NO:2. By failing to specify any human input or activity, the claim reads on a polypeptide as it exists in nature. Products of nature do not constitute patentable subject matter. This rejection may be obviated by recitation of an *isolated* polypeptide.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 is drawn to a polypeptide encoded by a nucleic acid according to claim 8, said nucleic acid being " a nucleic acid encoding a polypeptide according to claim 1". This circular definition suggests that the polypeptide of claim 23 is the same as that of claim 1, in which case claim 23 is subject to objection for failing to further limit the independent claim. If the polypeptide is meant to be something different from the polypeptide of claim 1, there is no indication of what the difference might be. Thus the metes and bounds of the claim cannot be determined.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 23, 24, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All claims are dependent from claim 1, which is drawn to a GCR1 polypeptide, or a fragment, homologue, variant or derivative thereof. The specification (p. 10, lines 4-23) indicates that "GCR1 polypeptide" is meant to include "homologous sequences obtained from any source, for example related cellular homologues, homologues from other species and variants or derivatives thereof" and that polypeptides with as little as 50% identical over 30 amino acids of the reference sequence are considered homologues. Dependent claims 2-7 are drawn to polypeptides having at least 50%, 60%, 70%, 80%, 90%, or 95% sequence homology to a sequence shown in SEQ ID NO:2. There is no size limit given to the claimed "fragment" and any two consecutive amino acids would satisfy the limitation, "***a*** sequence shown in SEQ ID NO:2". The claims do not require that the polypeptide, fragment, variant, or homolog possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

12. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional

characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO: 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising *the* amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-7, 23, 24, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by PIR accession number JC1241, submitted by Hayzer *et al.*, 30 September, 1993. All claims are dependent from claim 1, which is drawn to a GCR1 polypeptide, or a fragment, homologue, variant or derivative thereof, wherein the representative species of GCR1 polypeptide is represented by SEQ ID NO: 2. The amino acid sequence set forth in JC1241 is 89.8% identical to SEQ ID NO: 2 over the full 137 amino acids, and thus it appears to be the rat homolog of GCR1 (see Appendix, alignment result 1). JC1241 is 100% identical to SEQ ID NO: 2 from amino acids 35-92 and therefore it comprises (as in claims 26 and 27) and has at least 95% homology to (as in claim 7) *a* sequence shown in SEQ ID NO: 2, thus meeting the limitations of all of the instant claims.

Conclusion

15. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
14 October 2005

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

APPENDIX

Mon Jun 20 14:39:06 2005

GenCore version 5.1.6
Copyright (c) 1993 - 2005 Compugen Ltd.

OM protein - protein search, using sw model

Run on: June 18, 2005, 16:19:49 ; Search time 38 Seconds
(without alignments)
346.887 Million cell updates/sec

Title: US-10-621-911A-2
Perfect score: 697
Sequence: 1 MNHTSQAPITAASGGQPPNY.....VVITIVSVIIIVLNAQNLHT 137

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 283416 seqs, 96216763 residues

Total number of hits satisfying chosen parameters: 283416

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : PIR_79:*
1: pir1:*
2: pir2:*
3: pir3:*
4: pir4:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	643	92.3	137	2	JC1241	beta-interferon-in

ALIGNMENTS

RESULT 1
JC1241
beta-interferon-induced protein - rat
C;Species: Rattus norvegicus (Norway rat)
C;Date: 30-Sep-1993 #sequence_revision 30-Sep-1993 #text_change 03-Mar-1995
C;Accession: JC1241; S16757
R;Hayzer, D.J.; Brinson, E.; Runge, M.S.
Gene 117, 277-278, 1992
A;Title: A rat beta-interferon-induced mRNA: Sequence characterization.
A;Reference number: JC1241; MUID:92347706; PMID:1639276
A;Accession: JC1241
A;Molecule type: mRNA
A;Residues: 1-137 <HAY>
A;Cross-references: GB:X61381
A;Experimental source: aortic smooth muscle
A;Note: the authors translated the codon GCG for residue 9 as Val, ACA for residue 10 a

Query Match 92.3%; Score 643; DB 2; Length 137;
Best Local Similarity 89.8%; Pred. No. 1.1e-60;
Matches 123; Conservative 8; Mismatches 6; Indels 0; Gaps 0;

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Qy          1 MNHTSQAPITAASGGQPPNYERIKEEYEVAEMGAPHGSASVRTTVINMPREVSVPDHVVW 60
              ||||||||  | |:||||||||||||||||:|:||||||||||||||||||||||||||
Db          1 MNHTSQAFATVATGGQPPNYERIKEEYEVSELGAPHGSASVRTTVINMPREVSVPDHVVW 60

Qy         61 SLFNTLFMNFCCLGFIAYAYSVKSRDRKMVGDVTGAQAYASTAKCLNISTLVLSILMVVI 120
              ||||||||||||||||||||||||||||||||:||||||||||||||:|||||||:|
Db         61 SLFNTLFMNFCCLGFIAYAYSVKSRDRKMVGDMTGAQAYASTAKCLNISSLVLSILMVII 120

Qy        121 TIVSVIIIVLNAQNLHT 137
              |||:|:|| |||  | |
Db        121 TIVTVVIIALNAPRLQT 137
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